IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION – CINCINNATI

UNITED STATES OF AMERICA,	:	Case No. 1:19-cr-81
	:	
Plaintiff,	:	Judge Matthew W. McFarland
	:	
v.	:	
	:	
ANTHONY RATTINI, et al.,	:	
	:	
Defendants.	:	
	:	

ORDER DENYING MOTION TO DISMISS (Doc. 78)

This case is before the Court on the Motion to Dismiss (Doc. 78) filed by Defendants Anthony Rattini, James Barclay and Miami-Luken (collectively, the "Miami-Luken Defendants"). The Miami-Luken Defendants seek dismissal of the Indictment on the grounds that the Government has unlawfully premised its prosecution on their alleged failure to comply with DEA guidance letters. The Court finds that the Indictment does not premise liability on such non-compliance, but instead on established precedent holding that any person, including registrants, may be held liable for conspiring to violate 21 U.S.C. § 841(a) through the knowing and intentional distribution and dispensing of controlled substances outside the scope professional practice and not for a legitimate medical purpose. Accordingly, the Motion to Dismiss the Indictment is **DENIED**.

I. FACTS ALLEGED IN THE INDICTMENT

Miami-Luken is a wholesale pharmaceuticals distributor located in Montgomery County, Ohio. (Doc. 7 at ¶ 1.) Anthony Rattini, Miami-Luken's President, was in charge of ensuring the company's compliance with federal and state drug laws. (*Id.* at ¶ 3.) James Barclay, the Compliance Officer, supervised Miami-Luken's compliance with federal and state drug laws. (*Id.* ¶ 4.)

Miami-Luken registered with the Drug Enforcement Administration ("DEA") and was therefore permitted to distribute Schedule II, III, IV, and V controlled substances. (*Id.* at ¶ 2.) A "controlled substance" means a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V, pursuant to 21 U.S.C. § 802(6). (*Id.* at ¶ 7.) Controlled substances are categorized under the Controlled Substances Act ("CSA"), 21 U.S.C. § 801, *et seq.*, based primarily on their potential for abuse. (*Id.* at ¶ 17.) Schedule II means the drug and other substances have a high potential for abuse. (*Id.*) Additionally, Schedule II controlled substances have stringent restrictions on their accepted medical usages, as abuse of the drug can lead to severe psychological or physical dependence. (*Id.*) Schedule III means the drug has potential for abuse and could lead to moderate or low psychological or physical dependence. (*Id.*) Schedule IV means there is a low potential for abuse and a low risk of dependence. (*Id.*) Lastly, Schedule V means there is a low potential for abuse. (*Id.*)

Oxycodone is a Schedule II narcotic that can be sold under its generic name, OxyContin, or Percocet. (*Id.* at ¶ 18.) Oxycodone is one of the strongest pain killers approved in the United States and is highly addictive. (*Id.*) Hydrocodone is also a

Schedule II drug. (*Id.* at ¶ 20.) Previously a Schedule III drug, the DEA changed the status of Hydrocodone due to its high potential for abuse and dependence. (*Id.*)

The majority of Miami-Luken's profits were from its wholesale distribution of controlled substances. (*Id.* at ¶ 1.) The DEA maintains certain requirements for its registrants handling controlled substances. For example, Miami-Luken is required to submit reports regarding all transactions related to the acquisition and distribution of Schedule II and III narcotic substances. (*Id.* at ¶ 10, citing, 21 C.F.R. § 1304.33.) Miami-Luken is also required to maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels. (*Id.* at ¶ 8, quoting 21 U.S.C. § 823(b)(1).) Miami-Luken must also report suspicious orders to the DEA. (*Id.*) Such orders are those which are "of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." (*Id.* quoting, 21 C.F.R. § 1301.74(b).) The above information is transmitted to the DEA's Automation of Reports and Consolidated Ordering System on a quarterly basis and maintained in a DEA database. (*Id.* at ¶ 10, citing, 21 C.F.R. § 1304.33.)

Similar to distributors, pharmacists and physicians who wish to distribute or dispense controlled substances must register with the Attorney General of the United States. (*Id.* at ¶ 12.) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by a practitioner. (*Id.* at ¶ 11.) "Distribute" means to deliver, other than by administering or dispensing a controlled substance. (*Id.*) Once registered, each medical professional is assigned a DEA registration number. (*Id.* at ¶ 12.) Medical professionals are then permitted to write prescriptions and dispense Schedule II, III, IV,

and V controlled substances within the limits set under 21 U.S.C. § 822(b). (*Id.* ¶ 13.) A physician must not prescribe and a pharmacist must not fill a prescription for controlled substances unless it is "issued for a legitimate medical purpose by an individual practitioner in the usual course of his professional practice." (*Id.* ¶ 14, citing 21 C.F.R. § 1306.04(a).)

Messrs. Rattini and Barclay, and through them, Miami-Luken, are alleged to have conspired with pharmacists, including Defendants Devonna Miller-West and Samuel Ballengee, and others to distribute controlled substances outside the scope of legitimate medical purpose and facilitate their diversion for illicit use. (Doc. 7 at ¶ 22, 23.) Miami-Luken distributed controlled substances to over 200 pharmacies in Ohio, West Virginia, Kentucky, Indiana, and Tennessee. (*Id.* ¶ 1.) This included distribution of millions of dosage units of oxycodone and hydrocodone to doctors and pharmacies in the Southern District of Ohio, Kentucky, and West Virginia. (*Id.* ¶ 24.)

One such pharmacy was Westside Pharmacy ("Westside"), located in Oceana, West Virginia. (*Id.* ¶ 5.) Oceana has a population of approximately 1,394 people. (*Id.* ¶ 34.) Westside was owned and operated by Ms. Miller-West. (*Id.* ¶ 5.) Ms. Miller-West was a licensed pharmacist in the state of West Virginia. (*Id.*) Similarly, Miami-Luken distributed to Tug Valley Pharmacy ("Tug Valley") located in Williamson, West Virginia. (*Id.* ¶ 6.) Mr. Ballengee, as a licensed pharmacist in West Virginia, owned and operated Tug Valley. (*Id.*)

To further the conspiracy, Miami-Luken allegedly failed to maintain effective controls against diversion of controlled substances, failed to report suspicious orders to

the DEA, and continued to ship the dangerous addictive drugs to pharmacies in rural Appalachia where the opioid epidemic was at its peak. (*Id.* ¶ 25.) While Miami-Luken had an internal control policy that monitored distribution threshold limits for its customers, the company routinely exceeded these limits. (*Id.* at ¶ 36, 39, 41, and 46.)

For example, Westside had an internal threshold limit of 6,000 dosage units of Oxycodone per month. (*Id.* at ¶ 36.) Yet, in March 2011, Miami-Luken distributed 68,400 dosage units of Oxycodone to Westside. (*Id.*) In May of 2011, 63,900 dosage units were distributed to Westside. (*Id.*) Even though Westside's Oxycodone purchases were flagged by Miami-Luken's system, it continued to distribute Oxycodone well past the threshold limit. (*Id.*) Miami-Luken distributed 50,300 dosage units to Westside in December 2012 and 54,700 units to Westside in January 2014. (*Id.*)

Miami-Luken is likewise alleged to have disregarded its internal controls for Tug Valley, owned and operated by Mr. Ballengee. Tug Valley began purchasing and receiving controlled substances from Miami-Luken in August 2008. (*Id.* at ¶ 37.) The internal limit for Tug Valley was 36,000 dosage units of Hydrocodone per month. (*Id.* at ¶ 39.) In September 2008, however, Mr. Ballengee purchased 120,700 dosage units. (*Id.* at ¶ 37.) This pattern of exceeding internal limits continued in December 2013 when Miami-Luken distributed 67,200 dosage units of Hydrocodone to Tug Valley. (*Id.* at ¶ 39.) Between 2008 and 2014, Miami-Luken distributed more than six million dosage units of Hydrocodone to Mr. Ballengee and Tug Valley. (*Id.* at ¶ 38.)

On July 17, 2019, the Government filed a one-count indictment charging the Miami-Luken Defendants, Ms. Miller-West and Mr. Ballengee with engaging in a

conspiracy to distribute and dispense controlled substances in violation of 21 U.S.C. § 841, pursuant to 21 U.S.C. § 846. (*Id.* at ¶ 22.)

II. STATUTORY AND REGULATORY FRAMEWORK

The statutory and regulatory framework in which distributors operate is essential to understanding the Miami-Luken Defendants' arguments for dismissal of the Indictment. Below is an overview of the Controlled Substances Act, material regulations promulgated thereunder, guidance issued by DEA Deputy Assistant Administrator Joseph T. Rannazzisi in the so-called "Rannazzisi Letters," and certain DOJ policy memos that inform the Miami-Luken Defendants' view of the Indictment.

A. The Controlled Substances Act ("CSA")

A "main objective" of the Controlled Substances Act is controlling "illegitimate traffic in controlled substances," by placing "substances in one of five schedules based on their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). "To prevent diversion of controlled substances with medical uses, the CSA regulates the activity of physicians. To issue lawful prescriptions of Schedule II drugs, physicians must 'obtain from the Attorney General a registration issued in accordance with rules and regulations promulgated by him.'" *Id.* (quoting 21 U.S.C. § 822(a)(2)). The CSA establishes a fully closed system of distribution of controlled substances, in which everyone from the manufacturer to the physician must register with the DEA.

1. Registration Requirements

The CSA treats the registration of manufacturers and distributors differently than physicians and pharmacies. *See* 21 U.S.C. § 823. When a prospective distributor seeks registration, the DEA "shall register" the applicant to distribute a controlled substance in Schedules I-V unless he determines the issuance of such registration is inconsistent with the public interest. *Id.* at § 823(b) & (e). The statute identifies five factors that must be considered to determine whether registration is in the public interest:

> (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
>
> (2) compliance with applicable State and local law;
>
> (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (4) past experience in the distribution of controlled substances; and
>
> (5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. § 823(b) & (e).

For physicians and pharmacies, the DEA "shall register" practitioners to dispense controlled substances if the applicant is authorized to dispense controlled substances under the laws of the State in which the applicant practices. 21 U.S.C. § 823(f). The DEA may deny registration, however, if its issuance would be inconsistent with the public interest. The factors that must considered when making that determination are:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f).

The CSA places limits on the authorized activities of a distributor. Namely, a distributor may not (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of its assigned quota. 21 U.S.C. § 823(c).

2. Offenses and Penalties under the Controlled Substances Act

The CSA's general criminal provision is contained in 21 U.S.C. § 841(a), which states in relevant part:

> Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—
>
> (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance . . . .

21 U.S.C. 841(a)(1). Also relevant here, section 846 of the CSA makes it unlawful for "[a]ny person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy." 21 U.S.C. § 846. In

this case, Defendants are charged with conspiring to violate §841(a)(1), in violation of 21 U.S.C. § 846.

Section 842 of the CSA addresses specific statutory violations by registrants. For example, the Miami-Luken Defendants direct the Court's attention to Section 842(a)(5), which states:

> It shall be unlawful for any person . . . to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II.

21 U.S.C. § 842(a)(5). All registrants, except for physicians who are not prescribing controlled substances for maintenance or detoxification, are required to maintain and report inventories and transactions to the DEA on a periodic basis. 21 U.S.C. § 827(a)(1) & (3). Further, all orders for controlled substances must be made on forms provided by the DEA, and these forms must be maintained for two years. 21 U.S.C. § 828(a) & (c).

Failure to make, maintain or furnish any record, report or order form is a violation of 21 U.S.C. § 842(a)(5) and is punishable by a $10,000 civil fine. If it is a knowing violation, then the maximum penalty is a misdemeanor, punishable by up to one year imprisonment and a $100,000 fine. 21 U.S.C. § 842(c)(1)(B) & (c)(2)(A).

B. <u>The CSA's Regulatory Framework</u>

The regulations promulgated under the CSA are codified in 21 C.F.R. § 1300.01 *et seq.* The regulations provide that physicians cannot issue a prescription unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R § 1306.04(a). "The responsibility for

the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* When a purported prescription is not issued in the usual course of professional treatment or for legitimate and authorized research, both the prescribing physician and any pharmacist who knowingly fills the purported prescription are subject to the statutory penalties. (*Id.*)

Of particular relevance to the instant motion is section 1301.74, which is cited in the Indictment, regarding a distributor's obligation to report suspicious orders. It states:

> (a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.
>
> (b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 U.S.C. § 1301.74(a) & (b). The Indictment alleges, for example, that when Miami-Luken's internal controls flagged large orders of oxycodone and hydrocodone from an unnamed "Pharmacy 3," the Miami-Luken Defendants failed to conduct any due diligence or report the suspicious orders to the DEA. (Doc. 7 at ¶ 42.)

Under 21 C.F.R. § 1304.33, DEA registrants must submit information about all transactions in which a Schedule II or Schedule III-N (narcotic) controlled substance is

acquired or distributed (i.e., from a supplier to a pharmacy). This information is then stored in a DEA database.

C. The "Rannazzisi Letters"

On September 27, 2006, the DEA issued a letter to distributors from DEA Deputy Assistant Administrator Joseph T. Rannazzisi. The letter's stated purpose was "to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces." (Doc. 78-2 at PageID# 518.) It reminded distributors that the CSA "uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances" and that registration also serves as "the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations." (*Id.*)

Mr. Rannazzisi referred to the statutory factors that the DEA must consider in deciding whether to revoke a distributor's registration, which are set forth in 21 U.S.C. § 823(e). The first of those factors is "the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels." (Doc. 78-2 at PageID# 519, referring to 21 U.S.C. § 823(e)(1).) The letter also cites distributors' additional obligation to report suspicious orders of controlled substances under 21 C.F.R. § 1301.74(b).

After citing these two obligations, Mr. Rannazzisi continues:

> Thus, in addition to reporting all suspicious orders, a distributor has statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate

> medical, scientific, and industrial channels. Failure to exercise such due diligence would, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.
>
> In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely upon the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823 requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

(Doc. 78-2 at PageID# 519.) To determine whether an order is legitimate, Mr. Rannazzisi recommended that distributors pose a series of ten non-inclusive questions to the pharmacies that they supply. (*Id.* at PageID# 520.)

On December 27, 2007, Rannazzisi sent a second letter that provided further guidance regarding distributors' due diligence obligation. It stated, for example:

> The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

(Doc. 78-2 at PageID# 523.) The 2007 Rannazzisi letter reiterated that "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration." (*Id.* at PageID# 524.)

The Miami-Luken Defendants take issue with the "due diligence" requirement

and the prohibition against the filling of suspicious orders set forth in the Rannazzisi letters. As discussed below, they argue the unilateral imposition of such requirements on distributors, which are not explicitly set forth in the CSA or its regulations, circumvented the rulemaking process of the Administrative Procedure Act (APA).

D. DOJ Policy Statements

On November 16, 2017, Attorney General Jeff Sessions issued a department-wide memorandum directing the DOJ to utilize the notice and comment procedures of the APA when purporting to create rights or obligations binding on members of the public or the agency. He explained:

> Not every agency action is required to undergo notice-and-comment rulemaking. For example, agencies may use guidance and similar documents to educate regulated parties through plain-language restatements of existing legal requirements or provide non-binding advice on technical issues through examples of practices to guide the application or interpretation of statutes or regulations. But guidance cannot be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch. Nor should guidance create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.

(Doc. 78-2 at PageID# 554.) Mr. Sessions also stated that it had come to his attention "that the Department has in the past published guidance documents—or similar instruments of future effect by other names, such as letters to regulated entities—effectively bind private parties without undergoing the rulemaking process." (*Id.*) He then advised that "[t]he Department will no longer engage in this practice." (*Id.*)

In December 2018, the DOJ amended its regulations to prohibit prosecutions based on noncompliance with guidance documents. The U.S. Attorney's Manual stated

in pertinent part:

> Criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation.

U.S.A.M. § 1-20.100; Doc. 78-2 at PageID# 561. The Manual, however, provided that guidance documents could be relevant to a prosecution. It stated:

> Where a guidance document describes a relevant statute or regulation, the Department may use awareness of the guidance document (or its contents) as evidence that the party had the requisite scienter, notice, or knowledge of the law. [...] Such usage does not give guidance documents the force of law. By contrast, the Department may not treat awareness of a legal interpretation in a guidance document as an admission that the guidance document is a correct interpretation of the binding legal requirements in a statute or regulation.

U.S.A.M. § 1-20.201; Doc. 78-2 at PageID# 562.

III. LEGAL STANDARD ON MOTION TO DISMISS INDICTMENT

When resolving a motion to dismiss an indictment, the Court accepts all factual allegations as true. *Universal Milk Bottle Serv. v. United States*, 188 F.2d 959, 962 (6th Cir. 1951). An indictment is "sufficient if it (1) contains the elements of the charged offense, (2) gives the defendant adequate notice of the charges, and (3) protects the defendant against double jeopardy." *United States v. Rankin*, 929 F.3d 399, 404–05 (6th Cir. 2019) (quoting *Valentine v. Konteh*, 395 F.3d 626, 631 (6th Cir. 2005)). The general description of the charged offense "must be accompanied with such a statement of the facts and circumstances as will inform the accused of the specific offence, coming under the general description, with which he is charged." *Hamling v. United States*, 418 U.S. 87,

117–18 (1974); *see also United States v. Landham*, 251 F.3d 1072, 1079-80 (6th Cir. 2001). The Sixth Circuit has instructed that "indictments are analyzed more carefully with respect to their descriptions of the acts comprising the 'core of criminality.'" *United States v. Holmes*, 975 F.2d 275, 285 (6th Cir. 1992) (quoting *Russell v. United States*, 369 U.S. 749, 764 (1962)).

Here, the Miami-Luken Defendants challenge the Indictment on the following grounds:

> 1) the plain language of the statute specifically exempts the conduct alleged in the [Indictment];
>
> 2) the standards which the [Miami-Luken] Defendants are alleged to have violated are administrative obligations promulgated in violation of the Administrative Procedures Act, and thus an administrative agency has created, by fiat, a criminal standard in violation of Separation of Powers;
>
> 3) the statute, as applied to the [Miami-Luken] Defendants, is constitutionally void for vagueness and the Rule of Lenity applies; and
>
> 4) the prosecution has impermissibly circumvented Congressional intent, and violated Supreme Court instruction, by charging a general crime with more stringent penalties when Congress specified a misdemeanor that directly addresses the conduct at issue in this case.

(Doc. 78 at PageID# 373-74.) The Court addresses each of these arguments, and the Government's responses to them, ad seriatim below.

IV. ANALYSIS

A. The Plain Language of the Statute

The Miami-Luken Defendants' first argument is that their conduct is exempted from prosecution under 21 U.S.C. § 841 pursuant to the statute's opening clause. That clause states: "Except as otherwise authorized by this subchapter, it shall be unlawful . .

. ." 21 U.S.C. § 841(a). As a registrant under Part C of the subchapter, Miami-Luken was authorized as a wholesale distributor to order and distribute Schedule II, III, IV and V controlled substances to pharmacies. *See* Indictment, at ¶ 2; *see also* 21 U.S.C. §§ 821(b) and 823(c). As a result, the Miami-Luken Defendants contend that their conduct, as alleged in the Indictment, falls within the "except as otherwise authorized by this subchapter" clause of § 841(a). This argument raises the question of whether registrants under the CSA are subject to the general criminal provision making it unlawful to distribute controlled substances set forth in § 841.

The Supreme Court addressed this precise question in *United States v. Moore*, 423 U.S. 122 (1975). *See Moore*, 423 at 124 ("The issue in this case is whether persons who are registered under the [CSA] can be prosecuted under s 841 for dispensing or distributing controlled substances.") In that case, the Supreme Court upheld a conviction under § 841(a) of a "pill mill" doctor who argued that (i) registered physicians may be prosecuted only under 21 U.S.C. §§ 842 and 843 and (ii) in any event, he could not be prosecuted under § 841 because his conduct was "authorized by (the) subchapter." *Id.* at 131. The doctor relied on the same language that the Miami-Luken Defendants rely on here—the opening clause of § 841(a)—and the Supreme Court recognized that the doctor's interpretation of the CSA "would even compel exemption from the provision of s 841 of all 'registrants,' including manufacturers, wholesalers, and pharmacists in addition to physicians." *Moore*, 423 U.S. at 143.

In *Moore*, the Supreme Court rejected the doctor's argument because "the scheme of the statute, viewed against the background of the legislative history, reveals an intent

[by Congress] to limit a registered physician's dispensing authority to the course of his 'professional practice.'" *Id.* at 140. Accordingly, the Supreme Court held that registered physicians can be prosecuted under § 841 "when their activities fall outside the usual course of professional practice." *Id.* at 124.

Since the Supreme Court's decision in *Moore*, the Sixth Circuit (along with every other circuit) has consistently held that a physician may be prosecuted under § 841 for distribution of controlled substances "outside the usual course of professional practice and for no legitimate medical purpose." *United States v. August*, 984 F.2d 705, 712 (6th Cir. 1992) (citing *United States v. Seelig*, 622 F.2d 207, 212–13 (6th Cir. 1980), cert. denied, 449 U.S. 869 (1980); *United States v. Varma*, 691 F.2d 460, 462 (10th Cir.1982); *United States v. Kirk*, 584 F.2d 773, 784–86 (6th Cir. 1978)). Similarly, pharmacists who fill prescriptions for controlled substances outside the usual course of professional practice have been held to violate 21 U.S.C. § 841. *See United States v. DeBoer*, 966 F.2d 1066, 1068–69 (6th Cir. 1992); *United States. v. Wiseberg*, 727 F. App'x 1, 5 (2nd Cir. 2018); *United States v. Steele*, 147 F.3d 1316 (11th Cir. 1998).

The Miami-Luken Defendants acknowledge this established precedent holding physicians and pharmacists liable under § 841 but note the absence of analogous caselaw as to registered wholesale distributors. The Government does not cite any such caselaw, instead arguing that *Moore*'s holding rationally extends to all registrants, including distributors, that make transactions "outside the legitimate distribution chain." (Doc. 86 at PageID# 726, quoting *Seelig*, 622 F.2d at 213 n.1; *see also* House Report No. 91-1444, 91st Cong., 2d Session, 1970 U.S. Code Cong. & Admin. News pp.

4566, 4569.) The Government's position is well-founded.

The Supreme Court's statutory analysis in *Moore* remains valid when applied to a registered distributor. The Supreme Court reasoned, for example, that "only the lawful acts of registrants are exempted" from § 841 because "[b]y its terms s 841 reaches 'any person.'" *Moore*, 423 U.S. at 131. Section 841, the Supreme Court observed, could have exempted "all registrants" or "all persons registered under this Act," but it did not. *Id.*

The Supreme Court noted that the CSA's drafters made distinctions between registrants and non-registrants where it intended for them to be treated differently:

> It is true that the term "registrants" is used in ss 842 and 843, and not in s 841. But this is of limited significance. All three sections provide that "(i)t shall be unlawful for any person . . . (to commit the proscribed acts)." Two of the eight subsections of s 842(a), one of the five subsections of s 843(a), and s 842(b) further qualify "any person" with "who is a registrant." The other subsections of ss 842 and 843 are not so limited. In context, "registrant" is merely a limiting term, indicating that the only "persons" who are subject to these subsections are "registrants." There is no indication that "persons" means "nonregistrants" when introducing the other subsections.

Id. at 133-34. Moreover, the definition of "practitioner" is consistent with this interpretation of the Act. That term is defined as one who is "registered . . . by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research." *Id.* at 141, citing 21 U.S.C. § 802(20) (now 12 U.S.C. § 802(21)). The definition both defines "practitioner" and describes "the type of registration contemplated by the Act." *Id.* at

141. That registration, observed the Supreme Court, "is limited to the dispensing and use of drugs "in the course of professional practice or research." *Id.* It does not authorize distribution, dispensing, or research involving a controlled substance outside the course of professional practice.

The Supreme Court also discussed the appellate court's reliance on Section 822(b), which provides: "Persons registered . . . under this subchapter to . . . distribute, or dispense controlled substances are authorized to possess, . . . distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." The appellate court construed this authorization to exclude a registrant's acts from prosecution under § 841. The Supreme Court disagreed: "This is a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons." *Id.* at 131. In addition, the subsection's heading, "Authorized activities" parallels the "Unlawful Acts" heading of §§ 841-843. The Supreme Court opined the "statutory language cannot fairly be read to support the view that all activities of registered physicians are exempted from the reach of s 841 simply because of their status." *Id.* at 131–32. Rather than exclude registrants from all criminal liability under § 841, which would have been "a sharp departure from prior laws," the Supreme Court inferred that § 822(b) was added to the CSA "to ensure that persons engaged in lawful activities could not be prosecuted." *Id.* at 132-33. The "Authorized activities" and "Unlawful Acts" sections thus were not mutually exclusive.

Although the defendant in *Moore* was a physician, the Supreme Court's analysis may be applied with equal force to any registrant under the CSA. The Government

therefore has the better argument regarding the statutory language of § 841.

Nevertheless, the Government makes a second point that is also dispositive of this issue. Namely, Defendants are charged with conspiring under § 846 to violate § 841 by distributing or dispensing controlled substances outside the scope of professional practice and not for a legitimate medical purpose. It is undisputed that pharmacies physicians are subject to prosecution under § 841. And, the language in § 846 is plain: "***Any person*** who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy." 21 U.S.C. § 846 (emphasis added). Section 846 does not have an opening clause subject to interpretation. "Any person" who conspires with a pharmacy to violate § 841 is subject to prosecution. As noted by the Government, this provision has been upheld in the prosecution of various individuals, regardless of whether they are registrants under the Act or have any medical training. *See United States v. Mahar*, 801 F.2d 1477, 1505 (6th Cir. 1986) (affirming conspiracy conviction for medical clinic president, pharmacist and medical clinic); *United States v. Johnson*, 831 F.2d 124, 130 (6th Cir. 1987) (affirming conspiracy convictions for nonpractitioners, including clinic director, who participated in conspiracy to sell prescriptions); *United States v. Elliott*, 876 F.3d 855, 864 (6th Cir. 2017) (affirming conviction under § 846 for a security guard at a clinic dispensing controlled substances). Thus, even if a registered distributor were not subject to § 841 directly, under established precedent and the plain language of § 846, it is subject to prosecution under § 846 for conspiring with a pharmacy or physician to violate § 841.

In conclusion, the plain language of § 841, as interpreted in *Moore*, does not exclude the Miami-Luken Defendants from prosecution. Moreover, the Miami-Luken Defendants are charged with engaging in a conspiracy to violate § 841. Their alleged co-conspirators include pharmacists and physicians who, under undisputed precedent, may be charged for violation of § 841 if they distribute or dispense controlled substances outside the usual course of professional practice and for no legitimate medical purpose.

B. Separation of Powers and the Administrative Procedures Act

The Miami-Luken Defendants argue that they are alleged to have violated standards that were not issued in accordance with the APA, which governs the process by which federal agencies may develop and issue regulations. Specifically, they contend that the Government seeks to hold them liable under ¶ 841 for violation of obligations set forth only in the Rannazzisi Letters.

The Government's response is simple—Defendants are not charged with violating the Rannazzisi Letters. The grand jury charged Defendants with conspiracy to knowingly and intentionally distribute and dispense controlled substances outside the scope of professional practice and not for a legitimate medical purpose, in violation of 21 U.S.C. §§ 841 and 846. To establish a conspiracy under § 846, "the government must prove, beyond a reasonable doubt, '(1) an agreement to violate drug laws, (2) knowledge and intent to join the conspiracy, and (3) participation in the conspiracy.'" *United States v. Robinson*, 547 F.3d 632, 641 (6th Cir. 2008), citing *United States v. Caver*, 470 F.3d 220, 232 (6th Cir. 2006) (quoting *United States v. Gibbs*, 182 F.3d 408, 420 (6th

Cir. 1999)). As previously discussed, it is well-established that, even if there is a question regarding registered distributors, registered pharmacists and physicians are subject to prosecution under § 841.

The Miami-Luken Defendants are correct that the Indictment contains allegations that they did not abide by the standards in the Rannazzisi Letters. If the Government were to prove these allegations at trial, however, it will not have met its burden of proof under § 846. It must prove a conspiracy to violate § 841, not a conspiracy to violate the standards set forth in the Rannazzisi Letters. The Indictment does not equate a violation of the Rannazzisi Letters with a violation of § 841. Nor has the Government argued that proposition in its papers here.

The parties have not asked the Court to rule on the relevance or admissibility of any evidence at this time. Without doing so, the Court notes that these allegations may be included in the Indictment to demonstrate the requisite scienter. Such use of guidance documents is expressly indicated in the United States Attorney Manual, which is cited in the Miami-Luken Defendants' opening brief. *See* U.S.A.M. § 1-20.201; Doc. 78-2 at PageID# 562 ("Where a guidance document describes a relevant statute or regulation, the Department may use awareness of the guidance document (or its contents) as evidence that the party had the requisite scienter, notice, or knowledge of the law.").

As the Miami-Luken Defendants are not charged with violating the Rannazzisi Letters or any other guidance document, their argument that the Indictment violates the APA or the separation of powers doctrine fails.

C. Void for Vagueness and Rule of Lenity

The Miami-Luken Defendants' arguments that the void for vagueness doctrine and Rule of Lenity apply are similarly based on the erroneous presumption that their liability is premised on violation of the Rannazzisi Letters. *See, e.g.*, Doc. 78 at PageID# 383 ("By utilizing the Rannazzisi Letters and its un-codified obligations, the Company Defendants had no fair and clear notice of what conduct was prohibited."). As discussed, the Indictment does not charge Defendants with violating those guidance documents, although awareness of such documents might be relevant to the Government's case. The relevant inquiry is whether §§ 841 and 846 are vague or ambiguous.

"[T]he rule of lenity only applies if, after considering text, structure, history, and purpose, there remains a grievous ambiguity or uncertainty in the statute such that the Court must simply guess as to what Congress intended." *Maracich v. Spears*, 570 U.S. 48, 76 (2013). Under the vagueness doctrine, a criminal statute must "define the criminal offense with sufficient definiteness that ordinary people can understand what conduct was prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement." *Kolender v. Lawson*, 461 U.S. 352, 357 (1983). When determining vagueness, the court must look to "whether the statute, either standing alone or as construed by the courts, made it reasonably clear at the time of the charged conduct that the conduct was criminal." *United States v. Lanier*, 520 U.S. 259, 259 (1997). Vagueness concerns "may be overcome in any specific case where reasonable persons would know that their conduct is at risk." *Maynard v. Cartwright*, 486 U.S. 356, 361 (1988).

Here, neither § 846 nor § 841 is ambiguous. Section 846 applies to "[a]ny person who attempts or conspires to commit any offense defined in this subchapter." 21 U.S.C. § 846. The term "any person" is not qualified. There is no ambiguity in § 846 itself.

The Court already discussed the opening clause of § 841, which the Miami-Luken Defendants claim is void for vagueness. Under the Supreme Court's construction in *Moore*, § 841 applies to registrants and non-registrants alike. And, since *Moore*, § 814 has been routinely applied to registrants whose conduct falls outside the usual course of professional practice and not for a legitimate medical purpose. *See supra* p. 17. The Government further notes that the Sixth Circuit and other circuits have already considered and rejected void-for-vagueness challenges to § 841. *See, e.g., United States v. DeBoer*, 966 F. 2d 1066, 1068–69 (6th Cir. 1992); *United States v. Birbragher*, 603 F.3d 478, 488 (8th Cir. 2010). The Miami-Luken Defendants thus cannot reasonably claim that there was any grievous uncertainty as to whether they could be prosecuted under §§ 846 and 841 for conspiring with pharmacies or physicians to dispense controlled substances outside the usual course of professional practice.

Finally, the Government persuasively argues that notice concerns are alleviated by the intent element of §§ 841 and 846. The Miami-Luken Defendants cannot be successfully prosecuted under § 846 without a showing, beyond a reasonable doubt, that they ***knowingly and voluntarily*** conspired to unlawfully distribute controlled substances. *See* Sixth Circuit Pattern Instructions No. 14.02A, 14.05. "[W]here the punishment imposed is only for an act knowingly done with the purpose of doing that which the statute prohibits, the accused cannot be said to suffer from lack of warning or

knowledge that the act which he does is a violation of law." *Screws v. United States*, 325 U.S. 91, 102 (1945). The Government must show that Miami-Luken knew and intended for its controlled substances to be dispensed in violation of § 841. A distributor cannot have such knowledge without understanding the criminal nature of its own conduct.

D. Whether Prosecution under 21 U.S.C. §§ 841 & 846 is Proper

The Miami-Luken Defendants contend they cannot be prosecuted under §§ 841 and 846 because Congress made the specific conduct alleged in the Indictment subject to less severe penalties under 21 U.S.C. § 842. (Doc. 78 at PageID# 387-89, citing *Dowling v. United States*, 473 U.S. 207 (1985).) In *Dowling*, the Supreme Court considered whether a provision of the National Stolen Property Act (NSPA) prohibiting the interstate transportation of goods "stolen, converted or taken by fraud" applied to the defendant's manufacture and transportation of "bootleg" Elvis Presley records. *Dowling*, 473 U.S. at 208. The conduct at issue was also a violation of the federal copyright laws, as the defendant did not have the copyright holders' consent to reproduce the musical compositions on the records.

The Supreme Court first observed that interference with copyright did not "easily equate with theft, conversion, or fraud." *Dowling*, 473 U.S. at 217. In light of this incongruence, the Supreme Court considered the history and purpose of the NSPA to determine if Congress intended for the statute to reach the interstate shipment of goods infringing copyrights. Put simply, it did not. The NSPA and its amendments targeted gaps in state law enforcement relating to auto theft and the "roving criminal," not the theft of intellectual property. *Id.* at 220. The Court further noted that Congress had

chiefly relied on civil remedies to protect copyright holders and acted with "a good deal of care . . . before subjecting copyright infringement to serious criminal penalties." *Id.* at 225. Congress gave no intention that it intended the NSPA to supplement its significant body of copyright law. Thus, "[i]nvoking the 'time-honored interpretive guideline' that 'ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity,'" the Supreme Court held the NSPA did not apply to the defendant's transportation of bootleg records. *Id.* at 229, quoting *Liparota v. United States*, 471 U.S. 419, 427 (1985) (internal quotes omitted).

The Miami-Luken Defendants argue that, as in *Dowling*, Congress addressed their conduct in another statute, namely 21 U.S.C. § 842, and has not clearly indicated an intent for that same conduct to be subject to § 841. More specifically, they contend that they are charged with the knowing failure to report suspicious orders, which Congress made a crime punishable by up to a $500,000 fine, but no imprisonment. (Doc. 78 at PageID# 388, citing 21 U.S.C. § 842(c)(1)(C) and 842(c)(2)(A), (D).) They also reference the allegation that Miami-Luken failed to maintain effective controls against diversion. Prior to 2018, neither the CSA nor its regulations imposed any civil or criminal penalty for failure to maintain such controls. 21 C.F.R. § 1307.71(a). Post 2018, it is subject to the same penalties as a failure to report suspicious orders. 21 U.S.C. § 842(c)(1)(C) and 842(c)(2)(A), (D).

The problem with the Defendants' argument, once again, is that they have mischaracterized the charges against them. They are not charged with failing to report suspicious order or failing to maintain effective controls—although those violations are

allegedly part of the overall conspiracy. The argument that this conduct must be charged under § 842 therefore fails. *See Moore*, 423 U.S. at 138 ("There is nothing in the statutory scheme or the legislative history that justifies a conclusion that a registrant who may be prosecuted for the relatively minor offense of violating § 829 is thereby exempted from prosecution under § 841 for the significantly greater offense of acting as a drug 'pusher.'")

V. CONCLUSION

As discussed above, the Miami-Luken Defendants' Motion to Dismiss fails in large part because it is premised on a mischaracterization of the crime for which they are charged. Their Motion to Dismiss is **DENIED**.

IT IS SO ORDERED.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

By: Matthew W. McFarland
JUDGE MATTHEW W. McFARLAND